UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE:	:	21-CV-8255 (JMF)
BRISTOL-MYERS SQUIBB COMPANY CVR SECURITIES LITIGATION	:	OPINION AND ORDER

JESSE M. FURMAN, United States District Judge:

In this litigation, a consolidated putative class action brought on behalf of those who purchased or otherwise acquired Contingent Value Rights ("CVRs") issued by Bristol-Myers Squibb Company ("BMS" or "Bristol") as part of a merger, Plaintiffs alleged that Defendants — BMS and current or former BMS executives and directors — violated the Securities Act of 1933, the Securities Exchange Act of 1934 (the "Exchange Act"), and Securities and Exchange Commission ("SEC") Rules promulgated thereunder. In a prior Opinion and Order, familiarity with which is presumed, the Court granted Defendants' motion to dismiss the First Amended Complaint, finding that — among other issues — Plaintiffs had failed to plead scienter. *See In re Bristol-Myers Squibb Co. CVR Sec. Litig.* ("*BMS I*"), 658 F. Supp. 3d 220 (S.D.N.Y. 2023) (ECF No. 110). With leave of Court, *see id.* at 239, Plaintiffs thereafter filed the operative Second Amended Complaint ("SAC"), ECF No. 115, adding allegations in an effort to address that defect. Although the SAC includes all of the claims and most of the Defendants from the prior pleading, Plaintiffs confirm that the only claims they are still pressing are those against BMS, Dr. Giovanni Caforio, and Dr. Samit Hirawat under Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and SEC Rule 10b-5, 17 C.F.R. § 240.10b-5. Defendants now move, pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, to dismiss those claims, arguing that, among other things, Plaintiffs still do not plausibly allege

scienter. *See* ECF No. 118. The Court agrees. Thus, and for the reasons that follow, Defendants' motion is GRANTED, and the SAC is dismissed.

BACKGROUND

The following facts, taken from the SAC, documents it incorporates by reference, and matters of which the Court may take judicial notice, are construed in the light most favorable to Plaintiffs. *See, e.g.*, *Kleinman v. Elan Corp., PLC*, 706 F.3d 145, 152 (2d Cir. 2013); *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007) (stating that a court may consider "legally required public disclosure documents filed with the SEC").

A. Relevant Facts

BMS is a publicly traded global pharmaceutical company. SAC ¶ 63. Dr. Caforio is BMS's Chief Executive Officer, and Dr. Hirawat is its Chief Medical Officer. *Id.* ¶ 13.

On January 2, 2019, BMS entered into a preliminary merger agreement with Celgene Corporation ("Celgene"), another pharmaceutical company, pursuant to which each share of Celgene common stock would be exchanged for one share of BMS common stock, fifty dollars in cash, and one CVR. *Id.* ¶ 122; *see* ECF No. 120-1 ("Joint Proxy"), at 3. According to the agreement, the CVRs would trade on a stock exchange and would pay out nine dollars per CVR — $6.4 billion in total — but *only if* three drugs that Celgene had been developing, Liso-cel, Ide-cel, and Ozanimod (together, the "Milestone Drugs"), were approved by the FDA by certain deadlines — in the case of Liso-cel, by December 31, 2020 (the "Liso-cel Milestone Deadline"). SAC ¶¶ 112, 123; *see also* Joint Proxy 4, 217-21. If even *one* Milestone Drug was approved *one day* late, the CVRs would expire worthless. *See* SAC ¶ 112. Celgene's shareholders voted to approve the merger on April 12, 2019. *Id.* ¶ 126. On November 20, 2019, the merger (the "Merger") closed and the CVRs were issued. *Id.* ¶ 25.

Celgene initiated the FDA approval process for Liso-cel before the Merger. *Id.* ¶ 127. After a series of setbacks and delays — the particulars of which are described in the Court's prior Opinion and Order, *see BMS I*, 658 F. Supp. 3d at 227-28, and need not be repeated here — the FDA's inspections of the two manufacturing facilities slated to produce Liso-cel were not completed until early December 2020, only weeks before the Liso-cel Milestone Deadline. *Id.* ¶¶ 142-43, 154. The FDA found multiple regulatory violations at both facilities, which required BMS to respond with remediation plans. *Id.* ¶¶ 145-49, 154-63. BMS fully responded by the FDA's mandated deadline of December 23, 2020, *id.* ¶ 166, but FDA approval of Liso-cel did not come until February 5, 2021 — roughly five weeks after the December 31, 2020 Liso-cel Milestone Deadline, *id.* ¶ 185. Accordingly, and notwithstanding the timely approvals of both Ozanimod and Ide-cel, the CVRs expired worthless. *Id.* ¶ 184.

Not surprisingly, litigation followed. First, in a case also pending before the undersigned, the CVR Agreement trustee sued BMS for breach of contract by failing to use "diligent efforts" to meet the Liso-cel Milestone Deadline. *See UMB Bank, N.A. v. Bristol-Myers Squibb Co.*, No. 21-CV-4897 (JMF) (S.D.N.Y. filed June 3, 2021). Second, Plaintiffs filed this putative class action.[1] Broadly speaking, Plaintiffs' surviving claims arise from statements made by Dr. Caforio, Dr. Hirawat, and BMS after the Merger "concerning the 'diligent' efforts [BMS] would make to meet the Milestone[Deadlines], the likelihood that the Milestone[Deadlines] would be met, and the purported value of the CVRs." SAC ¶ 9. They include statements made in presentations, press releases, earnings calls, and SEC filings between December 8, 2019, and

[1] In yet another case, removed from state court to this Court and then remanded, a CVR holder sued BMS for making false and misleading statements in a Registration Statement filed with the SEC in connection with the CVRs. *See Williams v. Bristol-Myers Squibb Co.*, No. 21-CV-9998 (JMF), 2022 WL 4345564 (S.D.N.Y. Sept. 19, 2022).

November 16, 2020. *See id.* ¶¶ 232-79. Plaintiffs' claims are all premised on the same theory: that "Bristol intended to slow-roll the FDA application process . . . so that it would miss at least one FDA milestone and avoid making the $6.4 billion CVR payment." *E.g.*, *id.* ¶ 231.

B. Procedural History

As noted, the Court previously granted Defendants' motion to dismiss the First Amended Complaint. As relevant here, the Court dismissed Plaintiffs' Section 10(b) and Rule 10b-5 claims on the ground that Plaintiffs had failed to adequately allege scienter. *See BMS I*, 658 F. Supp. 3d at 235. More specifically, the Court concluded first that Plaintiffs' "motive and opportunity" arguments fell short because the First Amended Complaint did not allege that any individual Defendant had personally benefited from any alleged misstatement. *See id.* at 231. It rejected Plaintiffs' reliance on the "'massive' size of the alleged fraud," individual Defendants' interest in "potential 'increases in the value of their millions of dollars' worth of [BMS] common stock,'" and "the fact that BMS 'refus[ed] to buy back any CVRs on the open market . . . [when] the CVRs were trading well below the $9 payout." *Id.* at 231-32. Next, the Court found Plaintiffs' "conscious misbehavior or recklessness" allegations wanting because they failed to demonstrate that any individual Defendant had actually known or should have known of the purported missteps that led to the delay of FDA approval. *See id.* at 232-35. Plaintiffs' allegations about "missteps during the Liso-cel approval process," generalized allegations by an "FDA Biologics Expert" and eight confidential witnesses about what individual Defendants should have known, and invocation of the "core operations doctrine" failed to give rise to an "inference of scienter at least as strong as any opposing inference." *Id.* (internal quotation marks omitted). The Court concluded that scienter had not been adequately alleged as to either the individual Defendants or BMS itself. *See id.* at 235. Given the absence of a "primary violation,"

the Court also dismissed Plaintiffs' "controlling person" claims under Section 20(a) of the Exchange Act. *See id.* at 238.

But the Court granted Plaintiffs leave to amend their Exchange Act and SEC Rule 10-b claims, *see id.* at 239, which Plaintiffs timely did. The SAC includes several sets of new allegations that, Plaintiffs contend, bolster the case for scienter. With respect to Defendants' motive and opportunity, it includes additional allegations regarding the importance of the Celgene merger and the approval of Liso-cel to BMS. *See* ECF No. 121 ("Pls.' Opp'n"), 15 (citing SAC ¶¶ 10-14, 19, 92-94, 105-114, 116-120, 173, 206). With respect to Plaintiffs' arguments concerning circumstantial evidence of scienter, the SAC provides "substantial new allegations demonstrating Bristol's corporate structure ensured that its leadership, including the Individual Defendants, knew about the Liso-cel submission and approval failures." *Id.* at 1. It also adds new allegations, most notably from their "FDA Biologics Expert" and from three new Confidential Witnesses ("CWs"), to the effect that BMS and the individual Defendants must have been aware of the various deficiencies in BMS's conduct throughout the FDA approval process. *See id.* at 2. And finally, it includes statistical analysis from the FDA Biologics Expert and allegations from the CWs purporting to show "that the missed Milestone date cannot be blamed on the COVID-19 pandemic or mere 'mismanagement.'" *Id.* at 2-3.

LEGAL STANDARDS

In reviewing a motion to dismiss pursuant to Rule 12(b)(6), a court must accept the factual allegations set forth in the complaint as true and draw all reasonable inferences in favor of the plaintiff. *See Giunta v. Dingman*, 893 F.3d 73, 79 (2d Cir. 2018). A court will not dismiss any claims unless the plaintiff has failed to plead sufficient facts to state a claim to relief that is facially plausible, *see Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007), that is, one that

contains "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged," *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). More specifically, the plaintiff must allege facts showing "more than a sheer possibility that a defendant has acted unlawfully." *Id.* A complaint that offers only "labels and conclusions" or "a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555. Further, if the plaintiff "ha[s] not nudged [his] claims across the line from conceivable to plausible, [those claims] must be dismissed." *Id.* at 570.

Because Plaintiffs allege securities fraud, they must also satisfy the heightened pleading requirements of the Private Securities Litigation Reform Act ("PSLRA"), 15 U.S.C. § 78u-4(b)(2), which requires that scienter — that is, a defendant's "intention to deceive, manipulate, or defraud" — be pleaded with particularity. *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 313 (2007) (internal quotation marks omitted); *see, e.g.*, *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 37 (2011) (noting that scienter is an element of a Section 10(b) and Rule 10b-5 claim); *SEC v. First Jersey Sec., Inc.*, 101 F.3d 1450, 1472 (2d Cir. 1996) (noting that, to state a control-person claim under Section 20(a), a plaintiff must, at a minimum, plead a plausible "primary violation" of Section 10(b)); *City of N. Miami Beach Police Officers' & Firefighters' Ret. Plan v. Nat'l Gen. Holdings Corp.*, No. 19-CV-10825 (JPO), 2021 WL 212337, at *11 (S.D.N.Y. Jan. 21, 2021) (holding that the plaintiffs failed to plead corporate scienter "because they have not proven that anyone 'whose intent could be imputed to the corporation acted with the requisite scienter'" (quoting *Teamsters Loc. 445 Freight Div. Pension Fund v. Dynex Cap. Inc.*, 531 F.3d 190, 195 (2d Cir. 2008))).

To satisfy the PSLRA's scienter requirement, a complaint must, with respect to each defendant and "'with respect to each act or omission alleged to [constitute securities fraud], state

with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.'" *ATSI Commc'ns*, 493 F.3d at 99 (quoting 15 U.S.C. § 78u-4(b)(2)); *see, e.g.*, *City of Omaha Police & Fire Ret. Sys. v. Evoqua Water Techs. Corp.*, 450 F. Supp. 3d 379, 419 (S.D.N.Y. 2020) ("[I]n a case involving multiple defendants, plaintiffs must plead circumstances providing a factual basis for scienter for each defendant . . . ."); *In re Lions Gate Ent. Corp. Sec. Litig.*, 165 F. Supp. 3d 1, 22 (S.D.N.Y. 2016) (noting that a plaintiff must "allege facts supporting a strong inference with respect to *each* defendant" (emphasis added)). The "strong inference" must be "more than merely plausible or reasonable." *Tellabs*, 551 U.S. at 314. The necessary inquiry is "inherently comparative." *Id.* at 323. That is, the Court "must consider plausible, nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff." *Id.* at 324. A complaint alleging securities fraud will survive "only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.*

In this Circuit, a plaintiff may satisfy the scienter pleading requirement in either of two ways: "by alleging facts (1) showing that the defendants had both motive and opportunity to commit the fraud or (2) constituting strong circumstantial evidence of conscious misbehavior or recklessness." *ATSI Commc'ns*, 493 F.3d at 99. The former requires a plaintiff to allege that the defendant "benefitted in some concrete and personal way from the purported fraud." *ECA, Loc. 134 IBEW Joint Pension Tr. of Chi. v. JP Morgan Chase Co.*, 553 F.3d 187, 198 (2d Cir. 2009) (quoting *Novak v. Kasaks*, 216 F.3d 300, 307-08 (2d Cir. 2000)). The latter requires allegations of either actual intent or "conscious recklessness — *i.e.*, a state of mind approximating actual intent, and not merely a heightened form of negligence." *Stratte-McClure v. Morgan Stanley*, 776 F.3d 94, 106 (2d Cir. 2015). More specifically, a plaintiff must allege conduct by a

defendant that is, "at the least, conduct which is highly unreasonable and which represents an extreme departure from the standards of ordinary care to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it." *Kalnit v. Eichler*, 264 F.3d 131, 142 (2d Cir. 2001) (internal quotation marks omitted). Notably, where "there is no evidence of motive, . . . the strength of the circumstantial allegations [of scienter] must be correspondingly greater." *Marcu v. Cheetah Mobile, Inc.*, No. 18-CV-11184 (JMF), 2020 WL 4016645, at *7 (S.D.N.Y. July 16, 2020) (internal quotation marks omitted).

DISCUSSION

Measured against the foregoing standards, the Court concludes that Plaintiffs' allegations of scienter still fall short. Given that the Court reached a similar conclusion in *BMS I* with respect to the allegations in the First Amended Complaint, the Court focuses here — as the parties do in their briefing — on the allegations that Plaintiffs added to the SAC.[2]

A. Motive and Opportunity

First, Plaintiffs' arguments with respect to the motive-and-opportunity prong of the scienter test fall short for the same reason they did before: They still fail to allege that the individual Defendants "benefitted in some concrete and personal way from the purported fraud." *ECA*, 553 F.3d at 198 (internal quotation marks omitted). Plaintiffs contend that they have added new allegations beyond the "massive" size of the alleged fraud, including "the enterprise-level importance of the Celgene merger; the importance of the incorporation of Celgene's therapies, including Liso-cel, on the success of the merger; the extraordinary press attention Liso-cel and

[2] Plaintiffs cite as evidence of scienter that BMS "executives regularly spoke in detail about the state of the Liso-cel approval process," Pls.' Opp'n 11-12, and "the significance of the Celgene merger" to the company, *id.* at 12-13. The Court rejected virtually identical arguments in its prior Opinion and Order, *see BMS I*, 658 F. Supp. 3d at 233 n.6, 234, and thus does not focus on them here.

the merger received; the recent underperformance in Bristol's stock and the slew of criticisms that had recently been levied against Defendant CEO Caforio and the rest of Bristol's leadership, and the recognition that the Celgene merger was seen as an opportunity to reverse that trend." Pls.' Opp'n 15. At bottom, however, these allegations add little to what Plaintiffs previously argued, namely that the individual Defendants had a motive to keep BMS's stock price high. *See BMS I*, 658 F. Supp. 3d at 231-32. But as the Court previously ruled, "'maintain[ing] a high stock price . . .' is a paradigmatic objective 'generally possessed by most corporate directors and insiders' and thus does not suffice." *Id.* at 231 (quoting *S. Cherry St., LLC v. Hennessee Grp. LLC*, 573 F.3d 98, 109 (2d Cir. 2009)).

Two additional considerations undercut Plaintiffs' motive-and-opportunity arguments. First, as the Court previously explained, "the absence of any allegation that the [individual] Defendants purchased additional shares of BMS stock during the lifespan of the CVRs undermines Plaintiffs' [theory], as the gravamen of [the theory] is that the [individual] Defendants knew, 'all [the] while,' that the Milestone Deadlines would be missed and, thus, that the market was underpricing BMS stock." *Id.* at 231-32 (quoting ECF No. 105, at 3, 19-20). Second, as Defendants note, *see* ECF No. 119 ("Defs.' Mem."), at 20, Plaintiffs' contention that Defendants were motivated to breach BMS's obligations in order to avoid the $6.4 billion CVR payments "defies economic reason." *ECA*, 553 F.3d at 203. That is because any failure to secure timely FDA approval was certain to trigger a lawsuit seeking equivalent damages for breach of the CVR agreement — as it did. *See UMB Bank, N.A. v. Bristol-Myers Squibb Co.*, No. 21-CV-4897 (JMF) (S.D.N.Y. filed June 3, 2021). Thus, the individual Defendants could not and would not have assumed that a deliberate plan to scuttle FDA approval by the Milestone Deadlines would have "spare[d] Bristol a . . . $6.4 billion payout," as Plaintiffs allege. SAC ¶ 7.

B. Strong Circumstantial Evidence of Conscious Misbehavior or Recklessness

As noted, where, as here, "there is no evidence of motive, . . . the strength of the circumstantial allegations [of scienter] must be correspondingly greater." *Marcu*, 2020 WL 4016645, at *7 (internal quotation marks omitted). Plaintiffs' new allegations are still not enough for them to meet this "demanding requirement[]." *Id.*

1. Corporate Structure

To begin, Plaintiffs contend that "the SAC features substantial new allegations demonstrating Bristol's corporate structure ensured that its leadership, including the Individual Defendants, knew about the Liso-cel submission and approval failures." Pls.' Opp'n 1. More specifically, Plaintiffs cite two categories of new allegations regarding "corporate structure": first, that the individual Defendants served on committees with oversight authority relating to the drug approval process and the Celgene integration, *see id.* (citing SAC ¶¶ 37-40, 178-82), and second, that there was "extensive direct communication between Bristol's senior personnel, including Defendant Caforio, and the FDA regarding the Company's Liso-cel submissions and approval process failures," *id.* (citing SAC ¶¶ 41, 46, 175). Neither category passes muster.

As to the first, it is well settled that "[m]ere membership in a committee with oversight responsibilities," which is all that Plaintiffs allege, "is not enough to give rise to an inference of recklessness." *In re Refco, Inc. Sec. Litig.*, 503 F. Supp. 2d 611, 653 (S.D.N.Y. 2007). As this Court has explained elsewhere, "general allegations about the responsibilities of [a] committee, and what its members might have learned, are, at bottom, speculative and, thus, insufficient to show scienter." *Africa v. Jianpu Tech. Inc.*, No. 21-CV-1419 (JMF), 2022 WL 4537973, at *11 (S.D.N.Y. Sept. 28, 2022). In arguing otherwise, Plaintiffs contend that "[c]ourts regularly find that corporate committee membership supports an inference of scienter regarding the information

within that committee's jurisdiction." Pls.' Opp'n 9. But the cases Plaintiffs cite do not support such a broad proposition. *See In re Peabody Energy Corp. Sec. Litig.*, No. 20-CV-8024 (PKC), 2022 WL 671222, at *22 (S.D.N.Y. Mar. 7, 2022) (finding a "strong inference of conscious recklessness" by members of a task force formed specifically to monitor the very issue that was the subject of the allegedly misleading statements in response to warning signs); *Venkataraman v. Kandi Techs. Grp., Inc.*, No. 20-CV-8082 (LGS), 2022 WL 4225562, at *7 (S.D.N.Y. Sept. 13, 2022) (finding "sufficient circumstantial evidence of recklessness or conscious misbehavior" based on allegations that, at a meeting, defendants gathered specific "facts or . . . information suggesting that their public statements were not accurate"); *In re Longwei Petroleum Inv. Holding Ltd. Sec. Litig.*, No. 13-CV-214 (HB), 2014 WL 285103, at *5 (S.D.N.Y. Jan. 27, 2014) ("The alleged failure [of an audit committee] to take any action in response to *acknowledged* reporting failures supports a finding of scienter." (emphasis added)); *In re Comverse Tech., Inc. Sec. Litig.*, 543 F. Supp. 2d 134, 144-45 (E.D.N.Y. 2008) (finding "that the 'red flags' evident on the face of the unanimous consent forms, *coupled with* [defendants'] likely experience and knowledge" based in part on their committee membership plausibly alleged scienter (emphasis added)).

Second, the SAC's new allegations do not support Plaintiffs' assertion "that numerous senior Bristol executives," including Dr. Caforio, "were in *direct communication* with the FDA regarding the Liso-cel approval process, and knew through both Bristol's FDA submissions and the direct communications from the FDA in response thereto" of the various alleged missteps during the approval process. Pls.' Opp'n 7. For example, the SAC alleges that FDA "inspection warning letters were regularly addressed to [Dr.] Caforio personally," but it attaches in support a letter pertaining to an entirely unrelated inspection. SAC ¶ 175. It also alleges that "letters

exchanged between the FDA and Bristol . . . cc'ed as many as *forty* individuals at Bristol, including senior executives from Global Regulatory Sciences, Global Risk Management, Global Drug Development, and Global Development Operations," but it conspicuously does not allege that the recipients included Dr. Caforio or Dr. Hirawat. *Id.* ¶¶ 41, 182. And it alleges that "*dozens* of Bristol employees attended the March and September 2020 meetings with the Center for Biologics Evaluation and Research ('CBER')" relating to the approval process, but once again fails to tie this allegation to any Defendant. *Id.* Even taken together, therefore, these allegations do not constitute strong circumstantial evidence of conscious misbehavior or recklessness.

2. New Expert and CW Allegations

Next, Plaintiffs cite added allegations from their FDA Biologics Expert and three new CWs in arguing that the individual Defendants "would have been aware of underlying issues regarding the FDA approval process for Liso-cel," SAC ¶ 47, 177, but these allegations also fail to nudge Plaintiffs' pleadings across the plausibility line.[3] They add opinions from the FDA Biologics Expert suggesting generally that in circumstances like the ones here, pharmaceutical executives would be aware of and be able to avoid the missteps that allegedly befell the Liso-cel approval process. *See, e.g.*, SAC ¶¶ 27, 29, 49, 146. These opinions, however, are no different from those the Court found wanting in the First Amended Complaint. They too do not speak to the knowledge of the individual Defendants specifically. And, again, it is well established that an expert may not opine on the state of mind or knowledge of a party. *See, e.g.*, *Anderson News, L.L.C. v. Am. Media, Inc.*, No. 09-CV-2227 (PAC), 2015 WL 5003528, at *2 (S.D.N.Y. Aug. 20,

[3] As in its earlier Opinion and Order, *see BMS I*, 658 F. Supp. 3d at 233 n.7, the Court need not decide whether or to what extent it may consider the FDA Biologics Expert's opinions or information from the CWs, as it would not affect the Court's analysis or conclusions.

2015), *aff'd*, 899 F.3d 87 (2d Cir. 2018); *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 479 (S.D.N.Y. 2016). Plaintiffs' new CW allegations fare no better. For starters, Plaintiffs still fail to allege that any of the CWs, new or old, had any "contact with the individual defendants that would be probative of [the] defendants' mental state." *Long Miao v. Fanhua, Inc.*, 442 F. Supp. 3d 774, 799 n.19 (S.D.N.Y. 2020); *see also Campo v. Sears Holdings Corp.*, 635 F. Supp. 2d 323, 335 (S.D.N.Y. 2009) (finding no scienter where the confidential witnesses cited in the complaint were not alleged to have interacted with the defendants), *aff'd*, 371 F. App'x 212 (2d Cir. 2010). And in any event, the allegations from CW #9 and CW #10 that the individual Defendants "would have been" kept apprised of updates regarding the approval process, SAC ¶ 47; *see id.* ¶ 177, and from CW #11 that his or her mid-December 2020 vacation would not have been approved had BMS thought there was a chance Liso-cel would be approved by the Milestone date, *id.* ¶ 165, fall far short of providing that the individual Defendants knew or should have known that their statements were false or misleading.

3. Statistical Analyses

Finally, Plaintiffs add new allegations and statistical analyses purporting to show that no alternative explanation for the delay in Liso-cel approval is more plausible than knowing misconduct on the part of Defendants. The analysis of their FDA Biologics Expert, they contend, shows that "there is a statistically significant difference between the 13-month approval time for Liso-cel and the approval times for [biologics that are directly comparable to Liso-cel]." *Id.* ¶¶ 203-05. They allege that this timeline "is a *statistical anomaly, even as compared to similar drugs undergoing the approval process during the COVID-19 pandemic*." *Id.* ¶ 205. But as the Court noted in dismissing the First Amended Complaint, "how the FDA handled other approvals during the pandemic has no bearing on Defendants' actions and knowledge —

Defendants did not determine the FDA's priorities and how it should deploy its resources during the pandemic." *BMS I*, 658 F. Supp. 3d at 235. Thus, allegations of this nature still do not give rise to a strong inference of scienter. Instead, they more likely support an inference of corporate (or government agency) "mismanagement," which is insufficient. *Fries v. N. Oil & Gas, Inc.*, 285 F. Supp. 3d 706, 721 (S.D.N.Y. 2018).[4]

CONCLUSION

For the foregoing reasons, the Court once again concludes that Plaintiffs' allegations fall short of establishing that the individual Defendants acted with the requisite scienter. And once again, the Court reaches the same conclusion with respect to BMS itself because the SAC "fail[s] to 'create a strong inference either (1) that someone whose intent could be imputed to [BMS] acted with the requisite scienter or (2) that the [alleged misstatements] would have been approved by corporate officials sufficiently knowledgeable about [BMS] to know that those statements were misleading.'" *Town of Davie Police Officers Ret. Sys. v. City of N. Mia. Beach Police Officers' & Firefighters' Ret. Plan*, No. 21-909-CV, 2021 WL 5142702, at *3 (2d Cir. Nov. 5, 2021) (summary order) (quoting *Loreley Fin. (Jersey) No. 3 Ltd. v. Wells Fargo Sec., LLC*, 797 F.3d 160, 177 (2d Cir. 2015)). Accordingly, Plaintiffs' Section 10(b) and Rule 10b-5

[4] On September 1, 2023, Plaintiffs filed a notice of supplemental authority, arguing that a then-recent opinion from the United States District Court for the Eastern District of Virginia — *In re James River Group Holdings, Ltd. Securities Litigation*, No. 21-CV-444 (DJN), 2023 WL 5538218 (E.D. Va. Aug. 28, 2023) — supports their position. *See* ECF No. 123. But *James River* is obviously not binding upon this Court. Nor does it support Plaintiffs position, substantially for the reasons set forth in Defendants' response. *See* ECF No. 124. In finding that the plaintiffs' allegations supported an inference of scienter when "[a]ssess[ed] . . . holistically," 2023 WL 5538218, at *19, the *James River* court emphasized, for example, that the executive defendants had been members of a "Reserve Committee," which had a "*specific* role in setting Commercial Auto Division reserves," and that they "received audit reports showing under-reserving of Uber claims" — the very subject of the allegedly misleading representations. *Id.* (emphases altered). As discussed above, no such specific allegations are present here.

claims must be and are dismissed for failure to adequately allege scienter.[5] It follows that Plaintiffs' "controlling person" claims must be and are dismissed as well. *See, e.g.*, *Ark. Pub. Emps. Ret. Sys. v. Bristol-Myers Squibb Co.*, 28 F.4th 343, 356-57 (2d Cir. 2022).

In a footnote, Plaintiffs request leave to amend their pleadings once again, citing the fact that, as of the time of briefing, they had "several outstanding FOIA requests" and that they "expect[ed] these requests to be fulfilled within weeks and thus would have additional information to further supplement their pleadings." Pls. Opp'n 25 n.30. That request is denied. "Where it appears that granting leave to amend is unlikely to be productive, . . . it is not an abuse of discretion to deny leave to amend." *Ruffolo v. Oppenheimer & Co.*, 987 F.2d 129, 131 (2d Cir. 1993). The Court already gave Plaintiffs a second opportunity to amend. *See BMS I*, 658 F. Supp. 3d at 239. On top of that, Plaintiffs fail to identify any facts in their possession that would cure the defects discussed above — even though nearly eight months have passed since they filed their brief and, thus, they have presumably received whatever documents they hoped to get in response to their FOIA requests. In light of the foregoing, the Court concludes that any amendment would be futile. *See, e.g.*, *Roundtree v. NYC*, No. 19-CV-2475 (JMF), 2021 WL 1667193, at *6 (S.D.N.Y. Apr. 28, 2021) (citing cases).

One final housekeeping matter remains. Under the PSLRA, the Court is required to "include in the record specific findings regarding compliance by each party and each attorney representing any party with each requirement of Rule 11(b) of the Federal Rules of Civil Procedure as to any complaint, responsive pleading, or dispositive motion." 15 U.S.C. § 78u-4(c)(1). Because all legal claims and defenses presented throughout this litigation were

[5] In light of that conclusion, the Court need not and does not reach Defendants' other arguments for dismissal, namely that Plaintiffs fail to allege any material misrepresentation, *see* Defs.' Mem. 11-18, and fail to plausibly allege loss causation, *see id.* at 23.

nonfrivolous under existing law and all factual contentions had evidentiary support or were reasonably based on belief or a lack of information, no sanctions under Rule 11 are warranted.

The Clerk of Court is directed to terminate ECF No. 118, to enter judgment for Defendants, and to close this case.

SO ORDERED.

Dated: February 29, 2024
New York, New York

JESSE M. FURMAN
United States District Judge